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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,214	08/10/2001	David Ager	00-629-B	4695

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

JONES, HUGH M

ART UNIT	PAPER NUMBER
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2128

DATE MAILED: 05/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,214

Applicant(s)

AGER ET AL.

Examiner

Hugh Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/17/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-19 of U. S. Application 09/927,214, filed 08/10/2001 are presented for examination.

Information Disclosure Statement

2. The information disclosure statement filed 12/17/2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because pages 949-950 of the Lindsey et al. paper are missing. Only pages 940-948 have been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

3. Please supply pages 949-950, which contain at least section "B" (Synthetic Application).

Drawings

4. Figures 6-10 should be designated by a legend such as –Prior Art– because only that which is old is illustrated. See MPEP § 608.02(g). These figures merely disclose known features of biochemistry. Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the

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page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 5 is objected to because of the following informalities: Claim 5 lacks a period. Appropriate correction is required.

Double Patenting

6. **Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16 or 23 of U.S. Patent No. 6,044,212 in view of Applicant's Own Admission.**

7. The claims are now disclosing only "*variables*" which affect chemical synthesis, whereas in the earlier application (08/862,840, now U. S. Patent 6,044,212), the variables were explicitly defined in the independent claims. The section entitled "Background of the Invention" (pp. 1-2, specification disclose):

"... The chemical reaction is affected by a wide range of physical variables. Since these variables are interdependent, the possible combinations and permutations of these variables are enormous ..." (Lines 17-19, pg. 1).

Furthermore:

"... These variables might include concentration, reaction times, temperature, type of reagents, amounts of reagents, etc. ..." (Lines 9-10, pg. 2).

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Thus, by Applicant's Own Admission, it was known those of ordinary skill in the art at the time of the invention that variables included concentration, reaction times, temperature, type of reagents, amounts of reagents, etc..

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. ("W": US Patent 5,981,267) in view of Lindsey et al. ("L": Applicant's IDS) and in further view of Patel et al. (US Patent 6,541,276).

11. Wong et al. disclose Enzymatic resolution of racemic mixtures and associated chemical techniques (such as use of polarimeters, HPLC). The specifics are provided below.

12. Wong et al. do not disclose the use of automated synthesis techniques.

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13. Lindsey et al. disclose automated synthesis and analysis of chemical solutions, including a robot controlled reaction well. The specifics are provided below.

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Wong et al. disclosure with the Lindsey et al. disclosure because Patel et al. disclose the techniques of combinatorial chemistry, synthesis and combinatorial libraries (col. 1, line 50 to col. 2, line and also disclose such techniques as applied to enzymatic resolution (col. 31, line 66 to col. 32, line 52).

15. Specifically, the cited art discloses:

A method for optimizing enzymatic resolution of a racemic mixture (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60) using a synthesizer, an analyzer and a computer (L: abstract; fig. 1-3; page 949 - section "B"), the method including the steps of:

identifying variables which affect enzymatic resolution (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60);

choosing a finite number of experimental tests, wherein the experimental tests have values for the variables (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60);

providing a plurality of wells (L: abstract; fig. 1-3);

assigning each of the experimental tests to a particular well (L: abstract; fig. 1-3);

dispensing reagents and solvents into a plurality of wells chosen from the values for the experimental tests (L: abstract; fig. 1-3);

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enzymatically resolving/transforming in the synthesizer using operating conditions chosen from the values for the experimental tests (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60),

obtaining at least a portion of contents from the plurality of wells (L: abstract; fig. 1-3);

analyzing to determine the magnitude of enzymatic resolution for the at least a portion of the contents from the plurality of wells (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60; L: abstract; fig. 1-3; page 949 - section "B");

automatically generating a statistical analysis using the computer based on the step of determining the magnitude of enzymatic resolution and at least one of the variables identified in order to evaluate the enzymatic resolution in the wells (L: abstract; fig. 1-3; page 949 - section "B"); and

automatically generating, using the computer, suggested parameters for future experiments based on the statistical analysis (L: abstract; fig. 1-3; page 949 - section "B").

wherein one of the variables is type of enzymes (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60; col. 7 – col. 15).

wherein one of the variables is amount of enzyme (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60).

wherein the variable for the type of enzymes is fixed (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60).

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wherein one of the variables is type of solvents (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60).

wherein the solvents are selected from the group consisting of MeCN, MeOH, EtOH, DMF, H₂O, aqueous buffers and mixtures thereof (W: col. 4, lines 5-23; col. 5, lines 44-53; col. 7 – col. 11).

wherein one of the variables is pH (W: Fig. 2-3; col. 3, line 53 - col. 4, line 23).

wherein one of the variables is type of substrates (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60; (especially W: col. 4, lines 5-23; col. 5, lines 44-53)).

wherein the step of analyzing to determine the magnitude of enzymatic resolution includes determining optical rotation of the at least a portion of the contents from the plurality of wells (W: col. 5, lines 29-32; col. 6, lines 59-62).

wherein the analyzer is a polarimeter (W: col. 5, lines 29-32; col. 6, lines 59-62).

wherein the analyzer is a chiral HPLC (W: col. 3, lines 59-61; col. 4, lines 61-63).

wherein carrying out of the enzymatic transformation of a compound is the enzymatic resolution of a racemic mixture (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60).

wherein the enzymatic transformation is a chemical transformation of a compound (W: Fig. 3; abstract; col. 1, lines 23-62; col. 2, lines 31-39; col. 4, lines 5-38; col. 5, lines 12-60).

wherein the step of analyzing the samples using the analyzer includes determining the amount of product yield (L: abstract; fig. 1-3; page 949 - section "B").

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wherein the step of analyzing the samples using the analyzer includes determining the amount of unreacted compound (L: abstract; fig. 1-3; page 949 - section "B").

wherein the step of automatically generating a statistical analysis includes ranking the plurality of wells based on the magnitude of enzymatic transformation (L: abstract; fig. 1-3; page 949 - section "B").

wherein the step of automatically generating a statistical analysis includes determining a most favorable reaction in one of the plurality of wells based on the magnitude of enzymatic transformation (L: abstract; fig. 1-3; page 949 - section "B").

16. Any inquiry concerning this communication or earlier communications from the examiner should be:

directed to:

Dr. Hugh Jones telephone number (703) 305-0023, Monday-Thursday 0830, to 0700 ET, **or** the examiner's supervisor, Kevin Teska, telephone number (703) 305-9704. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, telephone number (703) 305-3900.

mailed to: Commissioner of Patents and Trademarks

Washington, D.C. 20231

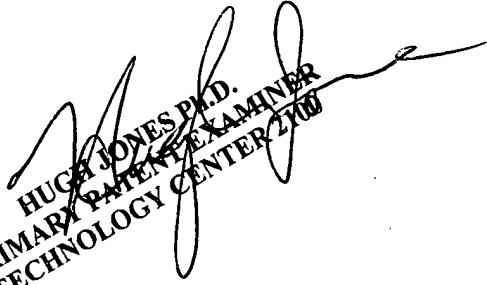
or faxed to: (703) 308-9051 (for formal communications intended for entry) **or**

(703) 308-1396 (for informal or draft communications, please label
APROPOSED or *ADRAFT*).

Dr. Hugh Jones

Primary Patent Examiner

April 27, 2005


HUGH JONES P.D.
PRIMARY PATENT EXAMINER
TECHNOLOGY CENTER 2100